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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2014-0340; FRL-9926-62]

Trinexapac-ethyl; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of trinexapac-ethyl in or on multiple commodities which are identified and discussed later in this document. Syngenta Crop protection LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2014-0340, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Susan Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: RDNRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).

- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2014-0340 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2014-0340, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of August 1, 2014 (79 FR 44731) (FRL-9911-67), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 4F8254) by Syngenta Crop Protection, LLC, P.O. Box 18300, Greensboro, NC 27419. The petition requested that 40 CFR 180.662 be amended by establishing tolerances for residues of the plant growth regulator trinexapac-ethyl, (4-(cyclopropyl-a-hydroxy-methylene)-3,5-dioxo-cyclohexanecarboxylic acid ethyl ester), and its primary metabolite CGA-179500 in or on rice, bran at 1.5 parts per million (ppm); rice, grain at 0.4 ppm; rice, straw at 0.07 ppm; rice, wild, grain at 0.4 ppm; rye, bran at 2.5 ppm; rye, grain at 2.0 ppm; rye, hay at 0.8 ppm; and rye, straw at 0.4 ppm. That document referenced a summary of the petition prepared by Syngenta Crop Protection LLC, the registrant, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has modified the proposed tolerances on rye commodities to rye, bran at 6.0 ppm; rye, grain at 4.0 ppm; rye, hay at 1.5 ppm; and rye, straw at 0.9 ppm. The reason for these changes are explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for trinexapac-ethyl including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with trinexapac-ethyl follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Trinexapac-ethyl exhibits low acute toxicity as shown in the standard acute toxicity battery as well as in the acute neurotoxicity study in rats with no systemic or neurotoxic effects up to the limit dose. The dog appears to be the most sensitive species while no systemic adverse effects were seen in rats, rabbits, or mice up to the limit dose (1,000 milligram/kilogram/day (mg/kg/day)) following subchronic or chronic oral exposure. In the dogs; however, decreased body weight gain and food consumption, diffuse thymic atrophy, and changes in the epithelial cells of the renal tubules were seen in the 90-day dog study at 516/582 mg/kg/day (males/females). Following chronic exposure, dose-related neuropathology of the brain characterized as focal bilateral vacuolation of the dorsal medial hippocampus and/or lateral midbrain was seen at $\geq 365/357$ mg/kg/day in male and female dogs, respectively. The lesions remained confined to the supporting cells in the central nervous system and did not progress to more advanced or more extensive damage of the nervous tissue. These lesions were not associated with other neuropathological findings or overt neurological signs, so their biological significance is unknown. Similar lesions were not observed in the rat or mouse following subchronic or chronic dietary exposure, and there was no other evidence in any other species tested to indicate a neurotoxicity potential. Furthermore, the brain lesions observed in the chronic dog study are not likely to develop from a short-term exposure and were not observed in either the rat or mouse short-term studies. In support of these findings, no evidence of neurotoxicity in the acute or subchronic rat neurotoxicity studies was found.

In the rat and rabbit developmental toxicity studies, there is evidence of increased qualitative and quantitative susceptibility in the rat (increased incidence of asymmetrical sternebrae at the limit dose) and rabbit (decreased number of live fetuses/litter and increased post-implantation loss and early resorption at 360 mg/kg/day) in the absence of maternal toxicity. Qualitative sensitivity was observed in the 2-generation reproduction study but only in excess of the limit dose (1,212 mg/kg/day). The decreased pup survival when analyzed with sexes combined, resulted in statistical significance (5-7%); this finding was not significant when the data were analyzed separately. Further evaluation of the individual litters suggested that one or two litters were the cause of the reduced pup survival at the highest dose tested. Reproductive toxicity was not observed up to the limit dose. There was also no indication of immunotoxicity in mice up to the limit dose.

Data from the combined chronic toxicity/carcinogenicity study in the rat did not demonstrate an increase in any tumor type that would be relevant to humans. The observation of squamous cell carcinomas in the non-glandular portion of the stomach of two males at 806 mg/kg/day does not provide reasonable evidence of a possible deleterious effect of trinexapac-ethyl on the pharynx and/or esophagus (non-glandular areas) of the human. This is because trinexapac-ethyl would not be in contact with human tissues for a significant period of time compared to the length of time it was in contact with the non-glandular portion of the rat stomach. Follicular adenocarcinomas of the thyroid were significantly increased in males (5%) at 806 mg/kg/day but this value was within the historical control range. In the mouse, there was no evidence of carcinogenicity. The mutagenicity database is complete, with no evidence of mutagenicity. The cancer classification for trinexapac-ethyl is "Not Likely to be Carcinogenic to Humans."

Specific information on the studies received and the nature of the adverse effects caused by trinexapac-ethyl as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in document “Trinexapac-ethyl: Human Health Risk Assessment to Support New Uses on Rice and Rye” on page 34 in docket ID number EPA-HQ-OPP-2014-0340.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for trinexapac-ethyl used for human risk assessment is discussed in Unit III B. of the final rule published in the **Federal Register** of March 2, 2012 (77 FR 12742) (FRL-9337-9).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to trinexapac-ethyl, EPA considered exposure under the petitioned-for tolerances (as revised in this regulation) as well as all existing trinexapac-ethyl tolerances in 40 CFR 180.662. EPA assessed dietary exposures from trinexapac-ethyl in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. Such effects were identified for trinexapac-ethyl. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 2003-2008 National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As to residue levels in food, EPA assumed that residues are present in all commodities at the tolerance level and that 100% of all commodities with trinexapac-ethyl tolerances are treated. The acute dietary exposure was only estimated for females 13 to 49 years old based on an *in utero* effect (decrease in mean number of fetuses/litter and an increase in post-implantation loss) identified in the rabbit developmental study. An endpoint of concern was not identified for the general U.S. population; however, the acute dietary assessment will ensure protection of women that may become pregnant.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 2003-2008 (NHANES/WWEIA). As to residue levels in

food, EPA assumed that residues are present in all commodities at the tolerance level and that 100% of all commodities with trinexapac-ethyl tolerances are treated.

iii. *Cancer*. Based on the data summarized in Unit III.A., EPA has concluded that trinexapac-ethyl does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information*. EPA did not use anticipated residue and/or PCT information in the dietary assessment for trinexapac-ethyl. Tolerance level residues and/or 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for trinexapac-ethyl in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of trinexapac-ethyl. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the Tier 1 Rice Model and Pesticide Root Zone Model Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCs) of trinexapac-ethyl for acute exposures are estimated to be 31.68 parts per billion (ppb) for surface water and 0.116 ppb for ground water. The EDWCs of trinexapac-ethyl for chronic exposures for non-cancer assessments are estimated to be 31.68 ppb for surface water and 0.054 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 31.68 ppb was used to assess the contribution to drinking water. For chronic dietary risk

assessment, the water concentration of value 31.68 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Trinexapac-ethyl is currently registered for the following uses that could result in residential exposures: Residential lawns, athletic fields, parks, and golf courses. EPA assessed residential exposure using the following assumptions: That homeowner handlers wear shorts, short-sleeved shirts, socks, and shoes, and that they complete all tasks associated with the use of a pesticide product including mixing/loading, if needed, as well as the application. Residential handler exposure scenarios for both dermal and inhalation are considered to be short-term only, due to the infrequent use patterns associated with homeowner products.

EPA uses the term “post-application” to describe exposure to individuals that occur as a result of being in an environment that has been previously treated with a pesticide. Trinexapac-ethyl can be used in many areas that can be frequented by the general population including residential areas (e.g., home lawns, recreational turf). As a result, individuals can be exposed by entering these areas if they have been previously treated. Therefore, short-and intermediate-term dermal post-application exposures and risks were also assessed for trinexapac-ethyl. There is the potential for dermal and incidental oral exposure to children; however, since there is no toxicological endpoint of concern for that route, a quantitative assessment was not conducted. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at <http://www.epa.gov/pesticides/trac/science/trac6a05.pdf>.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.” EPA has not found trinexapac-ethyl to share a common mechanism of toxicity with any other substances, and trinexapac-ethyl does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that trinexapac-ethyl does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

D. Safety Factor for Infants and Children

1. *In general*. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor (FQPA SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. Evidence of increased qualitative and/or quantitative susceptibility of the offspring was seen only at high doses in the developmental rat and rabbit studies, and in the rat reproduction study. Developmental toxicity in the rat was only

observed at the limit dose (increased incidence of asymmetrical sternebrae at 1,000 mg/kg) in the absence of maternal toxicity. In the rabbit, no maternal toxicity was demonstrated at the highest dose tested (360 mg/kg/day), but there was a decrease in the mean number of fetuses/litter and an increase in post-implantation loss and early resorptions at this dose level.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1x. That decision is based on the following findings:

- i. The toxicity database for trinexapac-ethyl is complete.
- ii. There is no indication that trinexapac-ethyl is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional Uncertainty Factor's to account for neurotoxicity.
- iii. Although, there is evidence of susceptibility in the rat and rabbit developmental studies and qualitative susceptibility in the 2-generation rat reproduction study, these effects only occurred at the highest doses tested for each study, and there were clearly identified NOAELs/LOAELs for the rabbit developmental study, the rat developmental study and for the reproduction study for each fetal/offspring effect. Therefore, there are no residual concerns with respect to developmental and reproductive effects.
- iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to trinexapac-ethyl in drinking water. EPA used similarly conservative assumptions to assess postapplication exposure of children as well as incidental oral exposure of

toddlers. These assessments will not underestimate the exposure and risks posed by trinexapac-ethyl.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. Therefore, acute aggregate risk is equivalent to the acute dietary risk as discussed in Unit III.C.1.i. All risk estimates are below EPA's level of concern. The acute dietary exposure estimate for females 13 to 49 years old will only utilize 2% of the aPAD, which is well below the Agency's level of concern (100% of the aPAD).

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to trinexapac-ethyl from food and water will utilize 6% of the cPAD for children 1 to 2 years old, the population group receiving the greatest exposure.

3. *Short- and intermediate-term risk:* Short- and intermediate-term aggregate exposure take into account short-term and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Trinexapac-ethyl is currently

registered for uses that could result in short- and intermediate-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term and intermediate-term residential exposures to trinexapac-ethyl. The short- and intermediate-term toxicological endpoints for trinexapac-ethyl are the same for each route of exposure. Therefore, for residential exposure scenarios, only short-term exposures were assessed, and are considered to be protective of intermediate-term exposure and risk.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 4500 for children 11-16 years old and 230 for adult females. Because EPA's level of concern for trinexapac-ethyl is a MOE of 100 or below, these MOEs are not of concern.

4. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, chemical name is not expected to pose a cancer risk to humans.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to trinexapac-ethyl residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (Method GRM020.01A, which utilizes high performance liquid chromatography with triple-quadrupole mass spectrometry (LC-MS/MS) is available to enforce the tolerance expression.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level. The Codex has not established a MRL for trinexapac-ethyl.

C. Revisions to Petitioned-For Tolerances

EPA revised the petitioned-for tolerances on rye which were determined by extrapolating from residue data on barley. EPA concurs with translating from the existing cereal grains, however, from a residue perspective, rye is more similar to wheat than to barley. Since the tolerances for wheat commodities are higher than the tolerances for barley commodities, EPA has revised the tolerances for rye to be consistent with the wheat tolerances. The use of the higher wheat tolerances also represents a more conservative (protective) approach for assessing risk from total residues.

V. Conclusion

Therefore, tolerances are established for residues of trinexapac-ethyl, (4-(cyclopropyl-a-hydroxy-methylene)-3,5-dioxo-cyclohexanecarboxylic acid ethyl ester), and the associated metabolite trinexapac, (4-(cyclopropylhydroxymethylene)-3,5-dioxocyclohexanecarboxylic acid), calculated as the stoichiometric equivalent of trinexapac-ethyl, in or on rice, bran at 1.5 ppm; rice, grain at 0.4 ppm; rice, straw at 0.07 ppm; rice, wild, grain at 0.4 ppm; rye, bran at 6.0 ppm; rye, grain at 4.0 ppm; rye, hay at 1.5 ppm; and rye, straw at 0.9 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a

proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: May 8, 2015.

G. Jeffery Herndon,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. Section 180.662, is amended by alphabetically adding the following commodities to the table in paragraph (a) to read as follows:

§ 180.662 Trinexapac-ethyl; tolerances for residues.

(a) * * *

Commodity	Parts per million
****	***
Rice, bran	1.5
Rice, grain	0.4
Rice, straw	0.07
Rice, wild, grain	0.4
Rye, bran	6.0
Rye, grain	4.0
Rye, hay	1.5
Rye, straw	0.9
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